

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Serial No.: 10/667,676  
Filed: September 22, 2003  
For: **SEQUESTERING SUBUNIT AND  
RELATED COMPOSITIONS AND  
METHODS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

May 24, 2010

**THIRD-PARTY SUBMISSION IN PUBLISHED APPLICATION (37 C.F.R. §1.99)**

Sir,

This is a submission pursuant to 37 C.F.R. § 1.99 of the patent listed on the accompanying Form PTO-1449 for consideration by the Examiner in the examination of the above-referenced application.

This submission is being made after two months from the date of publication of the above-referenced application and “is accompanied by (1) a satisfactory explanation why the patent[] ... being submitted in the submission could not have been submitted to the Office earlier, and (2) the processing fee as set forth in 37 CFR 1.17(i).” *See MPEP, section 1134.01 (I)*.

It is respectfully submitted that the listed patent could not have been submitted to the Office during the period specified in 37 C.F.R. § 1.99(e) (within the two months from the date of publication of the above-referenced application), e.g., because amendments submitted in the application after publication changed the scope of the claims to an extent that could not reasonably have been anticipated by a person reviewing the publication during the period specified in 37 C.F.R. § 1.99(e). For example, the claims were amended on February 4, 2010, more than two months after the July 8, 2004 publication, to recite “a blocking agent comprising a

surfactant, wherein the blocking agent substantially prevents release of the naltrexone from the sequestering subunit.” The term “surfactant” is only mentioned in paragraph [0114] of the publication in the lists of excipients of a liquid formulation or a capsule dosage form, and in paragraph [0061] of the publication in the list of gelling agents. There is however no description in the publication of a surfactant “substantially preventing release of the naltrexone” anywhere in the publication. Accordingly, the person reviewing the publication during the period specified in 37 C.F.R. § 1.99(e) could not have reasonably anticipated that the claims would be amended to recite “a blocking agent comprising a surfactant, wherein the blocking agent substantially prevents release of the naltrexone from the sequestering subunit.”

A copy of this submission was served on May 24, 2010, upon the Applicant’s attorney by first class mail, postage prepaid, addressed to an attorney of record at the following address:

Patrick J. Halloran, Ph.D., J.D.  
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The fees set forth in 37 C.F.R. §1.17(p) and 37 C.F.R. § 1.17(i) are being submitted concurrently herewith. The Commissioner is hereby authorized to charge any additional fees determined to be necessary in connection with the filing of this submission or credit any overpayment made in connection with this submission to our Deposit Account No. 50-0552.

Respectfully submitted,  
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By:   
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